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COMMISSION IMPLEMENTING DECISION (EU) 2023/2622

of 24 November 2023

not approving silver zinc zeolite as an existing active substance for use in biocidal products of product-type 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver zinc zeolite (CAS No: 130328-20-0) for product-type 4.

(2) Sweden was designated as the rapporteur Member State. Silver zinc zeolite has been evaluated by the competent authority of Sweden ('the evaluating competent authority') for use in biocidal products of product-type 4, food and feed area disinfectants, as referred to in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 4, food and feed area disinfectants, as referred to in Annex V to Regulation (EU) No 528/2012. In the application for approval, the applicant submitted a representative biocidal product intended for two example uses: the incorporation into polymers used in food contact materials to reduce cross contamination of pathogens and the incorporation into materials used in water filters to control the growth of bacteria.

(3) On 7 May 2012, the evaluating competent authority submitted the assessment report on the application together with the conclusions of its evaluation to the Commission. It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the provisions of Directive 98/8/EC. The European Chemicals Agency ('ECHA') discussed the assessment report and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of ECHA regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of ECHA on 3 March 2021 ([4]), having regard to the conclusions of the evaluating competent authority.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Biocidal Products Committee Opinion on the application for approval of the active substance: silver zinc zeolite, Product type: 4, ECHA/BPC/275/2021, adopted on 3 March 2021.

(5) It results from the conclusions of the opinion of ECHA that, concerning the incorporation of silver zinc zeolite into polymers used in food contact materials, sufficient efficacy has not been demonstrated. Furthermore, ECHA also concludes that unacceptable risks for human health have been identified from the consumption of food which has been in contact with treated polymers, and no adequate risk mitigation measure could be identified to mitigate those risks.

(6) As regards the incorporation of silver zinc zeolite into materials used in water filters, ECHA identified unacceptable risks for infants (6 to 12 months old) consuming water filtered through materials treated with silver zinc zeolite. The applicant proposed a risk mitigation measure in order to ensure that infants would not be exposed to silver zinc zeolite above the acceptable threshold, namely to restrict the use of treated water filters to commercial, hospitality and institutional establishments and prohibit residential use, including also a mandatory labelling of filters. However, the Biocidal Products Committee found this measure insufficient, as it cannot be excluded that infants are exposed to unacceptable levels of silver zinc zeolite via the consumption of filtered drinking water in restaurants and bars, especially when it comes to infants residing in the premises of bars and restaurants. There was no data submitted by the applicant in its dossier showing the sufficient risk reduction potential of such a measure. Data with respect to the in-house drinking water consumption of the general public versus outside the house (for example in restaurants and bars) or with respect to infants is lacking. There is no direct link between a warning given on the label, indicating that the impregnated water filter is for use in restaurants and bars only, and the objective of the measure (preventing the consumption by infants of drinking water which has passed through an impregnated filter). The Commission initiated a further consultation of Member States representatives on the matter in the Standing Committee on Biocidal Products, which further discussed the opinion of ECHA and additional arguments brought forward by the applicant on 3 May 2023. Member States representatives agreed with the opinion of ECHA and the Standing Committee on Biocidal Products concluded that there was not enough evidence to confirm that the risk mitigation measure proposed by the applicant would be sufficient to ensure that the risk to infants would be acceptable, while it could not identify any other adequate measure to mitigate the risk for infants for the use of water filters treated with silver zinc zeolite.

(7) In conclusion, unacceptable risks to human health are identified for each of the example uses of the representative biocidal product submitted in the application, and no safe use could be identified. Therefore, biocidal products of product-type 4 containing silver zinc zeolite are not expected to satisfy the criterion set out in Article 5(1), point (b)(iii) of Directive 98/8/EC read in conjunction with Article 10(1) of that Directive.

(8) Silver zinc zeolite has also been assessed pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). The European Food Safety Authority ('EFSA') adopted an opinion on 29 March 2005 ([6]) evaluating the safety of silver zinc zeolite A (i.e. silver-zinc sodium alumino silicate calcium metaphosphate with a silver content of 1-1,6 % and silver-zinc sodium magnesium alumino silicate calcium phosphate with a silver content of 0,34-0,54 %) for use in plastic food contact materials. That opinion concluded that a restriction of 0,05 mg/kg of food (as silver) for silver zinc zeolite A would limit the intake to less than 13 % of the human no observed adverse effect level, and therefore proposed a group-specific migration limit of 0,05 mg Ag/kg food with certain additional restrictions. Although silver zinc zeolite A has not been authorised for use in plastic food contact materials at Union level, it has been included in a provisional list of additives which can be used in plastic food contact materials subject to national law, in accordance with Article 6(5) of Commission Regulation (EU) No 10/2011 ([7]).

([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

([6]) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 7th list of substances for food contact materials (Question N° EFSA-Q-2003-076, EFSA-Q-2004-144, EFSA-Q-2004-166, EFSA-Q-2004-082, EFSA-Q-2003-204, EFSA-Q-2003-205, EFSA-Q-2003-206) adopted on 29 March 2005 by written procedure. The EFSA Journal (2005)201, p. 1-28.

([7]) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

(9) In the context of the evaluation of silver compounds under Regulation (EU) No 528/2012, EFSA and ECHA issued a joint document ([8]) in February 2020 (the 'joint EFSA-ECHA document'), in which they conclude that their respective opinions for the use of silver compounds in food contact materials are consistent within Regulation (EC) No 1935/2004 and Regulation (EU) No 528/2012, respectively, and that the differences in the risk assessment conclusions in their respective opinions are due to different objectives, datasets and methodologies.

(10) Taking into account the opinion of ECHA, as well as the joint EFSA-ECHA document, it is appropriate not to approve silver zinc zeolite as an active substance for use in biocidal products of product-type 4.

(11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Silver zinc zeolite (CAS No: 130328-20-0) is not approved as an active substance for use in biocidal products of product-type 4.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 24 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Joint EFSA – ECHA document of February 2020. Comparison of the evaluations performed on silver compounds used as biocidal active substances in food contact materials (FCM) by EFSA and ECHA.